EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 May 2018
EMA/71113/2018
EMEA/H/C/002777

Public statement

Olysio

Withdrawal of the marketing authorisation in the European Union

On 1 May 2018, the European Commission withdrew the marketing authorisation for Olysio (simeprevir) in the European Union (EU). The withdrawal was at the request of the marketing authorisation holder, Janssen-Cilag International NV, which notified the European Commission of its decision to permanently discontinue the marketing of the product for commercial reasons.

Olysio was granted marketing authorisation in the EU on 14 May 2014 for the treatment of chronic hepatitis C (CHC) in adult patients, in combination with other medicinal products. The marketing authorisation was initially valid for a 5-year period.

The European Public Assessment Report (EPAR) for Olysio will be updated accordingly to reflect the fact that the marketing authorisation is no longer valid.

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